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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,673	10/08/2004	Katsuyoshi Nagao	040520	6132
23850	7590	12/18/2006		
ARMSTRONG, KRATZ, QUINTOS, HANSON & BROOKS, LLP 1725 K STREET, NW SUITE 1000 WASHINGTON, DC 20006			EXAMINER WIEST, PHILIP R	
			ART UNIT 3761	PAPER NUMBER

DATE MAILED: 12/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/509,673

Applicant(s)

NAGAO ET AL.

Examiner

Phil Wiest

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3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 5-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/8/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 5-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Inoue et al. (US 5,423,421).

3. With respect to Claim 1, Inoue et al. disclose a multiple-chamber medical container comprising a container body 5 having chambers (1A, 1B, 7) capable of containing medicaments 10 therein, a partitioning seal portion (6c, 8a, 8b) for separating the chambers from one another, a medicinal outlet portion 2 attached to the container body 5 capable of discharging the medicaments, an openable small container 1a disposed in a larger chamber 7 and having a medicament 10 enclosed therein. Said partitioning seal portion (6c, 8a, 8b) is openable after the seal has been broken, enabling the chambers (1A, 1B) to communicate (Column 2, Lines 38-52) and is formed by bonding opposed inner wall surfaces together (Column 4, Lines 53-62). The sheet material 1 forming the small container 1A is bonded to the inner wall surfaces 6c of the container body on the right and left sides of the container 5 (see Figure 2). The small container 1A opens in accordance with the separation of the inner wall surfaces caused by the opening of the partitioning seal portion (6c, 8a, 8b) (Column 11, Lines 24-27).

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4. With respect to Claim 5, Inoue et al. disclose that the small container 1A is adjacent to the partitioning seal portion (6c, 8a, 8b). See Figures 1 and 2. Inoue et al. further disclose a distance of about 5mm between the small container 1A and the side wall 6.

5. With respect to Claim 6, Inoue et al. disclose that the small container 1A is heat-sealed (Column 4, Lines 12-15), with the partitioning seal portion (6c, 8a, 8b) being openable by external force (Column 11, Lines 24-27). Additionally, a portion of the small container 1A is bonded to the inner wall surfaces at the right and left sides of the container (Figures 1 and 2)

6. With respect to Claims 7 and 8, Inoue et al. disclose that the bonded portion (6c, 8a, 8b) of the small container 1A comprises a plurality of bonded parts. Said bonded portion (6c, 8a, 8b) further comprises a non-bonded part 9 which is provided in the center of the bonded portion (6c, 8a, 8b), as per Claim 8.

7. With respect to Claim 9 and 10, Inoue et al. disclose a multiple-chamber medical container wherein the sheet material 6 of the small container 34 comprises a multilayer film (Column 4, Lines 12-15), wherein the small container is opened by delaminating the multilayer film (Column 11, Lines 22-27). Inoue et al. further disclose that said sheet material is formed by laminating a plurality of layers (6c, 8a, and 8b) having low miscibility together. Said layers are laminated together at said partitioning seal portion (6c, 8a, and 8b). See Figures 1 and 4.

8. With respect to Claim 11, Inoue et al. disclose that the layers of the small container 1A are laminated by a heat-sealing process (Column 4, Lines 12-15). The

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sealed portion (8a, 8b) is able to be reopened by an external force. (Column 11, Lines 22-27). See Figure 4.

9. With respect to Claim 12, the small container 1A is disposed inside a larger chamber 7 and accommodates the medicament 10 in the chamber.

10. With respect to Claim 15, Inoue et al. disclose a powder 10 inside the small container 1A which may be an antibiotic (Column 9, Lines 52-54). Furthermore, the small container 1A is capable of holding any medicament selected from the group including antibiotics, anticancer drugs, cardiotonic drugs, vitamins, and trace elements.

11. Claims 3 and 17-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Larkin (US 4,602,910).

12. With respect to Claim 3, Larkin discloses a multiple-chamber medical container comprising a container body 20 having chambers (11, 34) capable of containing medicaments 51 therein, a partitioning seal portion 44 for separating the chambers from one another, a medicinal outlet portion (25, 26) attached to the container body 20 capable of discharging the medicaments, an openable small container 34 disposed in a larger chamber 11 and having a medicament 50 enclosed therein. Said partitioning seal portion 44 is openable after seal 43 has been broken, enabling the chambers (11, 34) to communicate (Column 4, Lines 9-21) and is formed by bonding opposed inner wall surfaces in a way such that they are separable (see Figures 4 and 5). The sheet material (36, 37) forming the small container 34 is bonded to the inner wall surfaces (15, 18) of the container body within the partitioning seal portion 44 (see Figure 4). The

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small container 34 opens in accordance with the separation of the inner wall surfaces (15, 18) caused by the opening of the partitioning seal portion 44 (see Figure 5).

13. With respect to Claim 17 and 18, Larkin discloses a multiple-chamber medical container 20 wherein the sheet material of the small container 34 comprises a multilayer film (15, 18, 36, 37), wherein the small container is opened by opened by delaminating the multilayer film. Larkin further discloses that said sheet material is formed by laminating a plurality of layers (15, 18, 36, 37) having low miscibility together, as per Claim 18. Said layers are laminated together at said partitioning seal portion 44. See Figures 4 and 5.

14. With respect to Claim 19, Larkin discloses that the layers of the small container are laminated by a heat-sealing process (Column 6, Lines 35-39). The sealed portion 44 is able to be reopened by an external force (Column 4, Lines 9-21). See Figures 4 and 5.

15. With respect to Claims 20 and 21, the small container 34 is disposed inside the large chamber 11 and accommodates the medicament 50 in the chamber (Column 3, Lines 39-41). Regarding Claim 21, Larkin further discloses that the medicament outlet portion (25, 26) is connected to the chamber 11 having the small container 34 disposed within. See Figure 1.

16. With respect to Claim 22, a discharge-control seal portion (27, 28, 32) is provided as an openable partition between the chamber 11 and the medicinal outlet portion (15, 16) (Column 3, Lines 53-56). See Figure 1.

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17. With respect to Claim 23, Larkin discloses that antibiotic powder 50 may be used as the medicament (Column 3, Lines 40-41). Furthermore, the small container 34 is container is capable of holding any medicament selected from the group including antibiotics, anticancer drugs, cardiogenic drugs, vitamins, and trace elements.

18. Claims 1, 3, 16, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Iguchi et al. (US 6,232,128). Iguchi et al. discloses a bag that is capable of enclosing at least one multiple-chamber medical container. Furthermore, said multiple-chamber medical container can be arranged in any position inside the bag.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al. in view of Larkin.

22. With respect to Claim 13, Inoue et al. disclose a multiple-chamber medical container comprising a container body 5 having chambers (1A, 1B, 7) capable of containing medicaments 10 therein, a partitioning seal portion (6c, 8a, 8b) for separating the chambers from one another, a medicinal outlet portion 2 attached to the container body 5 capable of discharging the medicaments, an openable small container 1a disposed in a larger chamber 7 and having a medicament 10 enclosed therein. Inoue et al., however, does not disclose that the medicinal outlet portion is in direct communication with the small container. Larkin discloses a multiple-chamber medical container wherein the medicinal outlet portion (25, 26) is connected to the chamber having the small container 34. It would have been obvious to one skilled in the art at the time of invention to combine the multiple-chamber bag of Inoue with the small container positioning of Larkin because the small container of Inoue is disclosed as being in fluid communication with the compartment comprising the fluid outlet. Since the exact placement of the small container does not affect the functionality of the system, placement within said compartment would have been obvious. Therefore, as disclosed by Larkin, the placement of a small, openable medicament container within a bag that is in fluid communication with the outlet is well known in the art.

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23. With respect to Claim 14, Inoue et al. disclose a multiple-chamber medical container comprising a container body 5 having chambers (1A, 1B, 7) capable of containing medicaments 10 therein, a partitioning seal portion (6c, 8a, 8b) for separating the chambers from one another, a medicinal outlet portion 2 attached to the container body 5 capable of discharging the medicaments, an openable small container 1a disposed in a larger chamber 7 and having a medicament 10 enclosed therein. Inoue et al., however, does not disclose a discharge-control seal to control flow out of the medicinal outlet portion. Larkin discloses a multiple-chamber medical chamber comprising a discharge-control seal (27, 28, 32) provided as an openable partition between the medicinal outlet portion (25, 26) and the chamber 11. It would have been obvious to one skilled in the art at the time of invention to modify the multiple-chamber medical container with the discharge control seal (27, 28, 32) of Larkin in order to prevent fluid flow through the outlet at an undesirable time. The use of a seal or valve at the fluid outlet of the bag is well known in the art.

Conclusion

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW
12/7/06

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

